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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/574,979	04/07/2006	Shigeru Chikase	2006-0391A	8777

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EXAMINER	
WESTERBERG, NISSA M	
ART UNIT	PAPER NUMBER
1618	
MAIL DATE	DELIVERY MODE
10/03/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/574,979	CHIKASE ET AL.	
	Examiner	Art Unit	
	Nissa M. Westerberg	1618	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 July 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1 - 11* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1 - 11* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *7/14/08*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' arguments, filed July 14, 2008, have been fully considered but they are not deemed to be fully persuasive. The following rejections and/or objections constitute the complete set presently being applied to the instant application.

Terminal Disclaimer

1. The terminal disclaimer filed on July 14, 2008 disclaiming the terminal portion of any patent granted on this application which would extend beyond the expiration date of any patent granted on Application 10/530,046 has been reviewed and is accepted. The terminal disclaimer has been recorded.

Claim Rejections - 35 USC § 112 – 2nd Paragraph

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

3. Claims 1 – 11 were rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed March 13, 2008 and those set forth below.

Applicant traverse this rejection by stating on p 6, ¶ 6 of the reply that the potency (efficacy) of cefditoren pivoxil is expressed as mass (potency) of cefditoren. Cefditoren pivoxil is an ester form of the active moiety of an antibiotic.

These arguments are not found to be fully persuasive. The amended claims remain unclear as the amount of the various ingredients which are present. For independent claim 1, the composition comprises cefditoren pivoxil and 0.1 – 200 mg of sucrose ester fatty acid on the basis of an amount equivalent to 100 mg of cefditoren pivoxil. From the explanation given by Applicant, it appears to the Examiner that the basis recited in the claim should be on the basis of the weight of cefditoren, not the ester form of cefditoren pivoxil. It remains unclear what amounts of the ingredients are required to be present as the efficacy only serves as "the basis". So it is unclear if Applicant is claiming a dosage form with any amount of cefditoren pivoxil but the amount of sucrose ester fatty acid must fall within a certain range when the amount of active ingredient is scaled to 100 mg efficacy or if Applicant is claiming a dosage form of 100 mg of cefditoren active moiety and 0.1 to 200 mg of sucrose ester fatty acid. These different interpretations are not clarified by the dependent claims.

Claim Rejections - 35 USC § 103

4. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

> invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

5. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

6. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

7. Claims 1, 3 – 7 and 9 – 11 were rejected under 35 U.S.C. 103(a) as being unpatentable over Kikkoji et al. (EP0629494) in view of JP 60132918. This rejection is MAINTAINED for the reasons of record set forth in the Office Action mailed March 13, 2008 and those set forth below. Due to the amendment to claim 1 requiring the active ingredient be present in the form of cefditoren pivoxil, this rejection is now applied to claims 1 – 11.

Applicant traverse this rejection on the basis that EP'404 does not refer to problem to be solved of the prevention of the conversion of cefditoren pivoxil from an amorphous form to a crystalline form in solution, nor is the prevention of this behavior by the inclusion of a sucrose ester fatty acid in the solid dispersion disclosed. JP'918 similarly fails to disclose this inhibition of crystallization in solution and at time of the instant filing, the understanding of one skilled in the art would understand that adding a surfactant would accelerate the crystallization of the ingredient. A supersaturated solution would form on the surface of the medicament upon dissolution of the surfactant containing medicament in an aqueous solution which, when moved away from the medicament, would generate a crystal.

These arguments are not found to be persuasive. JP'918 uses a sucrose fatty acid ester to improve oral absorbability while EP'494 uses hydroxypropylcellulose to counteract the decreased water wetability, disperability and solubility of the more fat-soluble cefditoren pivoxil without an increase in the bitterness of the composition. Rationale different from that of Applicant's is permissible as a rationale for combining references (see MPEP 2144). While the cited prior art may not have been seeking to solve the problem of crystallization of cefditoren pivoxil in aqueous solutions, the composition comprising cefditoren pivoxil, a sucrose ester fatty acid and hydroxypropylcellulose taught by the prior art to increase the oral absorbability will necessarily also have the properties of inhibiting crystallization. Applicant's statements regarding the generalized crystallization behavior are found to be mere allegations which are not found to be persuasive as they are without factual support.

Conclusion

8. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nissa M. Westerberg whose telephone number is (571)270-3532. The examiner can normally be reached on M - F, 8:00 a.m. - 4 p.m. ET.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Hartley can be reached on (571) 272-0616. The fax phone

number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Michael G. Hartley/
Supervisory Patent Examiner, Art Unit 1618

NMW